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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/109,082 | 07/02/1998 | JUDITH MELKI | 2121-140P | 3158 |

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| EXAMINER |
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HAYES, ROBERT CLINTON

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| ART UNIT | PAPER NUMBER |
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1647

DATE MAILED: 02/17/2004

32

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/109,082

Applicant(s)

MELKI ET AL.

Examiner

Robert C. Hayes, Ph.D.

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21,23,30-34 and 40-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 40-45,47,49-52,54 and 55 is/are allowed.
- 6) ☒ Claim(s) 21,23,30-34,46,48,53,56-60 and 62-70 is/are rejected.
- 7) ☒ Claim(s) 61 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner. *see paper #18*
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendments filed 1/29/03, 4/17/03, 6/26/03 and 7/18/03 have been entered.
2. The rejections of claims 30-34, 36, 43, 47, 48, 53, 64 & 65 under 35 U.S.C. 112, second paragraph, as being indefinite are withdrawn due to either the cancellation or amendment of the claims, or due to Applicants' arguments.
3. Claims 40-45, 47-52 & 54-55 are allowed.
4. Claim 61 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
5. Applicant's arguments filed 1/29/03 and 6/26/03 have been fully considered but are not deemed to be persuasive.
6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
7. Claims 21, 23, 30-34, 53, 57, 64-67 & 70 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a

Art Unit: 1647

way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record in Paper NOs: 20 (mailed 9/13/01) & 25 (mailed 7/29/02), and as follows.

In contrast to Applicants arguments in their response, the proper conception of using "a set of primers" is illustrated in originally submitted claim 16 using *specific pairs* of primers (i.e., as it relates to claims 21, 30, 57, 64-65, 67-68 & 70). Moreover, no proper antecedent basis nor conception in context with that described within the specification at the time of filing the instant application exists for broadening the primers to be used to "consisting essentially of", especially where random "insertion or deletion or mutation" are contemplated or described, in contrast to that argued on page 12 of the 6/26/03 response (i.e., as it relates to claims 21, 30 & 65-67). Likewise, no proper conception is apparent for using "inverted complementary sequences to SEQ ID NOs: 5 to 8" or for "a complement" thereof (i.e., as it relates to claims 67 & 68); thereby, also constituting new matter.

Note that amending claim 46 to "using the primer pairs consisting of SEQ ID NOs: 5 and 6, or SEQ ID NOs: 7 and 8, respectively" should place claim 46 in condition for allowance.

Second, the hybridization conditions recited are not commensurate in scope with that disclosed at the time of filing the instant application because the wash conditions are not recited, and it is the wash conditions that ultimately determine the stringency of the hybridization (i.e., as it relates to claims 23, 33-34 & 53); thereby, constituting new matter.

8. Claims 21, 23, 30-32, 46, 53, 57-60, 62-65 & 66-70 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting specific

Art Unit: 1647

motor disease states related to specific mutations of specific nucleotide sequences (i.e., by SEQ ID NO) using structurally definable probes or pairs of probes (i.e., by SEQ ID NO) and known restriction enzymes to generate detectable and definable polymorphisms, does not reasonably provide enablement for any generic method, or kit, that does not identify the specific disease state being detected, using structurally uncharacterized probes that may or may not identify specific portions of undefined or unknown genes, or unknown and undescribed polymorphisms thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons made of record in Paper NOs: 18 (mailed 1/30/01) & 20 (mailed 9/13/01) & 25 (mailed 7/29/02), and as follows.

As previously made of record, without identifying what pair of primers to be used to detect known and defined gene “truncations, deletions or mutations” in “kits” or in the recited “methods”, one of ordinary skill in the art would not know how to make and use Applicants’ invention, as currently claimed, for the reasons previously made of record. For example, any random primer or “complement” of a given primer sequence would replicate in either the same direction or opposite directions, and therefore, not give rise to a double stranded fragment amenable to PCR, restriction digest, etc. (i.e., as it relates to claims 21, 30, 46, 53, 57, 64-68 & 70). Thus, Applicants’ arguments remain not persuasive for the reasons made of record.

It is suggested that amending claims 58-60 to “T-BCD541 gene consisting of SEQ ID NO: 22...” should place claims 58-62 in condition for allowance, where it is further suggested that amending claim 62 to “by [direct] nucleotide sequencing” would reflect more conventional

Art Unit: 1647

claim language. Likewise, claim 69 is suggested to be amended to the “the Survival Motor Neuron gene which consists of SEQ ID NO: 22...”.

9. Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

SEQ ID NO: 22 is a “nucleotide” sequence versus an amino acid sequence. In addition, it is ambiguous whether steps (a)-(c) are missing, or whether the recited steps are misnumbered.

10. Claims 32, 56 & 63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

No antecedent basis for the recitation of “step (c)” in base claim 30 exists. Likewise, in claims 56 & 63 no antecedent basis exists for the recitation of “following *isolation*” in base claims 54 & 58, respectively.

11. Claims 53 & 23 stand rejected under 35 U.S.C. 102(b) as being anticipated by Stratagene Cloning Systems Catalog (1994).

In contrast to Applicants’ assertions on pages 14-15 of the 1/29/03 response, claim 53 recites “wherein the kit *comprises* a probe which comprises at least 9 nucleotides... [and which] hybridizes with a sequence of SEQ ID NOs: 1, 2 or 10-13”. In other words, the current claim does not limit the probes to sequences within SEQ ID NO: 12 or 13. Thus, because Stratagene’s

Art Unit: 1647

kit "comprises" oligonucleotides that structurally meet the limitation of probes "which comprise at least 9 nucleotides", and which "hybridize" to nucleotides sequences, Applicants' arguments are not persuasive for that currently claimed.

In summary, Stratagene disclose a kit (catalog #300385) that comprises purified random 9-mer oligonucleotide primers/probes, which inherently hybridize to SEQ ID NOs: 1, 2, 10-13 or 22. In that Stratagene's kit comprises the same products (i.e., probes) as that recited in claim 53, and because any intended uses of detecting SMA carries no patentable weight, as claimed, the limitations of claim 23 are also met.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

Art Unit: 1647

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (571) 272-0887. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.
February 12, 2004



PATRICIA A. DUFFY
PRIMARY EXAMINER